JAN 3 0 2004

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Axis-Shield Diagnostics Ltd.
The Technology Park
Dundee DD2 1XA
Scotland, UK
Tel : +44 1382 422000

Contact Person: Judith Finlayson

Date Prepared : January 28, 2004

Device Name

Proprietary Name:	Abbott AxSYM ® B-Type Natriuretic Peptide (BNP) Microparticle Enzyme Immunoassay (MEIA) test
Common name:	BNP test
Classification name:	Test, Natriuretic Peptide

Device Description

A device for the measurement of human B-Type Natriuretic Peptide (BNP) in EDTA plasma.

Intended Use

The quantitative determination of human B-type natriuretic peptide in human EDTA plasma on the AxSYM System. BNP values are used as an aid in the diagnosis and assessment of severity of heart failure.

510(k) Summary

Substantial equivalence

The AxSYM BNP immunoassay is substantially equivalent to the Biosite Triage BNP Test cleared under K021317. Both products are intended for use in the quantitative determination of B-type natriuretic peptide.

Substantial equivalence - comparison

The following information as presented in the Premarket Notification [510(k)] for AxSYM® BNP constitutes data supporting a substantially equivalent determination.

AxSYM BNP is a Microparticle Enzyme Immunoassay (MEIA) for the quantitative determination of BNP in human EDTA plasma. AxSYM BNP is calibrated with AxSYM BNP Standard Calibrators. AxSYM BNP Controls are assayed for the verification of the accuracy and precision of the Abbott AxSYM system.

Substantial equivalence has been demonstrated between the AxSYM BNP assay and the Biosite Triage® BNP test device. The intended use of both BNP assays is for the quantitative determination of human B-type natriuretic peptide (BNP) in human EDTA plasma. BNP values are used as an aid to the diagnosis assessment of severity of heart failure. Both assays are immunoassays that use antibodies specific for BNP. A Passing Bablok regression analysis between these two assays using 313 specimens with BNP values ranging from 0 to 3426 pg/mL, yielded a correlation coefficient of 0.956, a slope of 1.12 (95% Confidence Interval of 1.08 to 1.18) and a y-axis intercept of -8 (95% Confidence Interval of -6 to -9). Using a decision threshold of 100pg/mL for both tests, the concordance between the two assays was 91.4% (95% Confidence Interval of 87.7% to 94.2%).

In conclusion, these data demonstrate that the AxSYM BNP assay is as safe and effective as, and is substantially equivalent to the Biosite Triage BNP test device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 3 0 2004

Judith Finlayson, Ph.D.
Regulatory Affairs Manager
Axis-Shield Diagnostics
The Technology Park
Dundee DD2 1XA
Scotland, UK

Re: k033606
Trade/Device Name: Abbott AxSYM® B-Type Natriuretic Peptide (BNP) Microparticle Enzyme Immunoassay (MEIA)
Regulation Number: 21 CFR 862.1117
Regulation Name: B-type natriuretic peptide test system
Regulatory Class: Class II
Product Code: NBC; JIT; JJX
Dated: November 13, 2003
Received: November 17, 2003

Dear Dr. Finlayson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

4. INTENDED USE

510 (k) number K033606

Device Name

Abbott AxSYM ® B-Type Natriuretic Peptide (BNP) Microparticle Enzyme Immunoassay (MEIA)

Indications for Use

AxSYM ® BNP is a Microparticle Enzyme Immunoassay (MEIA) for the quantitative determination of human B-type natriuretic peptide in human EDTA plasma on the AxSYM System. BNP values are used as an aid in the diagnosis and assessment of severity of heart failure.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

.....

Concurrence of XDRH, Office of Device Evaluation (ODE)

Carol C Benson for Jean Cooper

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033606

Prescription Use ✓ ..... OR Over-the-Counter Use .....

Per 21 CFR 801.109

Option format 1-2-96